Remarks

Reconsideration of this Application is respectfully requested.

Claims 91-101, 103, 107, and 110-120 are pending in the application, with 91 and 103 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and request that they be withdrawn.

Information Disclosure Statement

The Examiner stated, in Paper 23, that the English translation of a Japanese patent submitted in the IDS filed April 10, 2003 was not considered because it does not contain a date and place of publication. The Examiner also stated that,

> the date of any resubmission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing of the statement.

(Paper 23, at p. 2.)

As discussed in the Amendment and Reply filed January 2, 2004, 37 C.F.R. § 1.98(a)(3)(ii) specifically requires that Applicants submit to the PTO any written English translation of a non-English document that is in Applicants' possession or control. Applicants could find no requirement in the rules or the MPEP that the

translation have a date or place of publication in order to be considered by the PTO. Applicants consulted with Cindy Nessler, OPLA Legal Advisor, to verify that there is no requirement that the English translation have a date and place of publication in order to be considered by the Examiner. Therefore, the Office Action is in error and Applicants respectfully request consideration of the English translation, IDS Document AR37, and making the same of record in this application.

Rejections under 35 U.S.C. § 112 - Written Description

Claims 91-101, 103, 107 and 110-120 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner has again taken the position that the claims encompass 684^{20} molecules, and the specification does not disclose a representative number of species. Applicants respectfully disagree with the rejection.

As recently reiterated by the Federal Circuit, the crux of the question concerning whether a claimed invention is adequately described is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention in the specification as filed. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)); *see also* M.P.E.P. § 2163.02. The Federal Circuit in *Eli Lilly* set forth several tests for whether a claimed genus is adequately described, including the "representative number of species" test and the "common structural features" test. *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). However, the court also stated that "[w]e will not speculate in what

other ways a broad genus of genetic material may be properly described." *Id.* (emphasis added).

In fact, subsequent to *Eli Lilly*, the Federal Circuit instructed that *functional* descriptions of biological material can satisfy the written description requirement if a structure/function correlation is known in the art. *See Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003).[1] The Federal Circuit has also reasoned, in reference to the recitation of known biological materials, that a description of a genus by words alone is sufficient if one of ordinary skill could recognize the members of the genus. *Amgen* at 1332. In addition, the Federal Circuit and the PTO have acknowledged that a specification may adequately describe a genus even though it fails to describe a single species falling within the genus. *Eli Lilly* at 1406; MPEP 2163 (II)(A)(3)(a)(ii) at p. 2100-169, col. 1.

Thus, there is no fixed set of tests for whether a claimed genus is adequately described. Instead, the determination of compliance with the written description requirement is a fact-based one, and in cases subsequent to *Eli Lilly*, the Federal Circuit has limited the holding in *Eli Lilly* to its particular set of facts. *E.g.*, *Moba* at 1320[2]; *Amgen* at 1332[3]; *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed.

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1 "*Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." (citation omitted).

2 "Invoking § 112, *Lilly* required a precise definition of a DNA sequence in the patent specification. *In more recent cases, however, this court has distinguished Lilly.*" (emphasis added).

3 "Both *Eli Lilly* and *Enzo Biochem* are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend."

Cir. 2002); *but see University of Rochester v. G.D. Searle & Co., Inc.*, Slip. Op. 03-1304 (Fed. Cir. Feb. 13, 2004).

In the present case, the specification clearly conveys that the inventors contemplated the claimed genus of substitution mutants. As discussed in previous replies, the specification describes a broad genus of enzymes, as well as specific examples, that could serve as the backbone for making the recited substitutions of the invention. These "backbone" sequences need not have been provided in the specification because they were known. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94 (holding that the description only needs to describe what is new or not conventional); MPEP 2163, p. 2100-165, col. 2 (Rev. 1, Feb. 2003).

The fact that new MMLV reverse transcriptases may be made in the future that may serve as the backbone to Applicants' claimed mutations is irrelevant, contrary to the Examiner's assertion in Paper 23 and in the Advisory Action. The Federal Circuit has instructed specifically that this line of reasoning simply is not relevant to compliance with the written description requirement of § 112. *See Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) ("The written description inquiry . . . focuses on a comparison between the specification and the invention referenced by the terms of the claim--*not comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made.*" (emphasis added) (quoting the district court opinion with approval)).

In view of the above remarks, reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. § 112 - Enablement

Applicants respectfully request clarification as to whether the rejection under 35 U.S.C. §112, first paragraph, for alleged lack of enablement was withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and request that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply to Advisory Action is respectfully requested.

Respectfully submitted,

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